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Docket No.: 04280/000M988-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Sai L. SU

Application No.: 10/009,508
Filed: ~~November 6, 2001~~ AUGUST 15, 2002

Art Unit: 1643

Examiner: Stephen L. RAWLINGS

For: METHODS FOR THE DIAGNOSIS AND TREATMENT OF METASTATIC PROSTATE TUMORS

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed July 19, 2005.

Applicant notes that this Office Action was incorrectly mailed to a predecessor law firm. Under the Revocation Of Power Of Attorney And Statement Under 37 C.F.R. § 3.73(b), filed September 2, 2003 (copy attached), the attorneys and agents of Darby & Darby have been appointed to prosecute this application. Accordingly, please address all future correspondence to Paul F. Fehlner, Esq. at Darby & Darby, PC, P.O. Box 5257, New York, New York 10150-5257.

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. § 121 and § 372:

Group I Claims 1-5, 7, 8 and 11, directed to a method for detecting a prostate cell having metastatic potential, which comprises detecting the expression of flt-4 in a prostate cell using an antibody or a portion thereof that binds flt-4;

Group II Claims 1-4, 6-8 and 11, directed to a method for detecting a prostate cell having metastatic potential, which comprises detecting the expression of flt-4 in a prostate cell using a nucleic acid consisting of at least six contiguous nucleotides of the complement of SEQ ID NO:1;

Group III Claim 12, directed to a method for determining the prognosis of a subject with prostate cancer, which comprises identifying a prostate cancer cell in a body fluid sample obtained form the subject and detecting the expression of flt-4 in the cell;

Group IV Claims 13-15, directed to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, which comprises administering to a subject a fragment of flt-4 consisting of at least the amino acid sequence represented by SEQ ID NO:2;

Group V Claims 13 and 16, directed to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, which comprises administering to a subject a nucleic acid encoding a fragment of flt-4;

Group VI Claims 13, 17 and 18, directed to treating, inhibiting or preventing a secondary prostate tumor metastasis, which comprises administering to a subject an antisense oligonucleotide consisting of at least six contiguous nucleotides of the complement of SEQ ID NO:1;

Group VII Claims 13 and 19, directed to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, which comprises administering to a subject an antibody or portion thereof that binds flt-4;

Group VIII Claim 20, directed to a method for screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis, which comprises contacting a

prostate cancer cell with a candidate molecule and comparing the level of expression of flt-4 in the cell with the level of expression in a cell not so contacted;

Group IX Claims 21 and 22, directed to a method for screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis, which comprises measuring the levels of complex formed from flt-4 and VEGF-C in the presence and absence of a candidate molecule;

Group X Claims 23, directed to a method for monitoring the efficacy of treatment or inhibition of metastatic prostate cancer, which comprises measuring the level of expression or activity of flt-4 in prostate cells obtained from a subject;

Group XI Claims 24 and 25, directed to a composition comprising a fragment of flt-4 consisting of at least the amino acid sequence of SEQ ID NO:2;

Group XII Claim 26, directed to a composition comprising a nucleic acid encoding a fragment of flt-4;

Group XIII Claims 27 and 28, directed to a composition comprising an antisense oligonucleotide consisting of at least six contiguous nucleotides of the complement of SEQ ID NO:1; and

Group XIV Claim 29, directed to a composition comprising an antibody or a portion thereof that binds flt-4.

Solely to be responsive to the requirement for restriction, Applicant provisionally elects to prosecute the invention of Group XIV (claim 29), directed to a composition comprising an antibody or a portion thereof that binds flt-4, with traverse.

Applicants respectfully request reconsideration of the Restriction Requirement or, in the alterative, modification of the Restriction Requirement to allow prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. § 121 "two or more independent and distinct inventions ... in one application may ... be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803).

Applicants respectfully submit that the Groups designated by the Examiner fail to define products and methods for using such products with technical features so distinct as to warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. In particular, claims 1-5, 7, 8, 11, 13 and 19 of Groups I and VII incorporate the use of the antibody composition of claim 29 *per se* and thus should not be restricted out of the Group XIV claims (claim 29) for the purpose of examination.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application, in particular those of Groups I, VII and XIV, is appropriate and would not present an undue burden on the Examiner, and accordingly, withdrawal of all or a portion of the Requirement for Restriction is believed to be in order. Accordingly, modification of the Requirement for Restriction and examination of at least Groups I, VII and XIV is respectfully requested.

The Examiner is respectfully reminded that if Group XIV is solely prosecuted, upon allowance of the Group XIV claim (claim 29), claims to the method of use of the claim 29 antibody

composition, such as the claims of Group I and Group VII, should be rejoined according to the Commissioner for Patent's "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Conclusion

It is believed that this paper is fully responsive to the outstanding Restriction Requirement. Accordingly consideration of these remarks is respectfully requested.

Dated: August 19, 2005

Respectfully submitted,

By _____

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